REMARKS/ARGUMENTS

Upon entry of this amendment, claims 10, 11, 20 and 21 will be canceled without prejudice or disclaimer of the subject matter recited therein, claims 1-3, 5, 7, 9, 12-15, 17-19, 22, 24 and 25 will be amended, whereby claims 1-3, 5, 7, 9, 12-15, 17-19, 22, 24 and 25 will be pending. Claims 1, 7, 12, 13, 14 and 17 are independent claims.

Reconsideration and allowance of the application are respectfully requested.

Consideration Of Information Disclosure Statements

Applicants express appreciation for the inclusion with the Office Action of an initialed copy of the Form PTO-1449, whereby the Examiner's consideration of the Information Disclosure Statement filed March 13, 2006 is of record.

Applicants note that the Examiner has crossed through U.S. Patent No. 4,960,773 as apparently not being material to the claimed subject matter. In this regard, Applicants submitted a copy of this document to make of record information cited in an Office Action mailed October 24, 2005 in Application No. 10/962,557 over which an obviousness-type double patenting has been maintained in the instant Office Action and which application was cited in the Third Supplemental Information Disclosure Statement filed August 26, 2005.

Applicants are submitting herewith a copy of JP 4-36107 B (as well as a copy of JP 61-205637 A and a family member list) in accordance with the Examiner's request. In this regard, it is noted that the previously submitted copy of JP 4-36107 was, in fact, a

copy of a similar number that was laid open as a category A document, and not copy published as a B category document. Accordingly, the record is being clarified to submit correct copies of the A and B category documents. Moreover, a Form PTO-1449 is submitted herewith listing JP 61-205637 so that the face of the issued patent will correctly reflect such consideration.

Applicants are also submitting a copy of the English translation and English abstract of JP 2001-130927 accompanied by the date-stamped mailroom receipt evidencing the filing of these documents on March 13, 2006.

Applicants are submitting a Form PTO-1449 listing the JP 2001-130927 and its English translation and English abstract. The Examiner is respectfully requested to initial the form and forward an initialed copy with the next communication from the Patent and Trademark Office.

A fee should not be necessary; however, if any fee is required, authorization is hereby provided to charge any required fee to Deposit Account No. 19-0089.

Response To 35 U.S.C. 112, Second Paragraph, Rejection

In response to the rejection of claims 1-3, 5, 9-12, 15 and 20-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, Applicants respectfully submit the following.

Initially, Applicants note that the independent claims have been amended to recite a sintered calcium phosphate comprising a bioactive glass as a sintering aid, and dependent claims have been amended in accordance with these changes to the independent claims.

Moreover, the independent claims have amended to amended to recite that the sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapapite, a carbonated apatite or tricalcium phosphate.

Still further, claims 10, 11, 20 and 21 have been canceled.

Accordingly, the 35 U.S.C. 112, second paragraph, rejection should be withdrawn.

Response To Anticipation, Obviousness and Double Patenting Rejections

(a) Rejection of claims 1,5, 10, 12, 14, 15, 18, 20-22, 24 and 25 under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Pfeil et al. (hereinafter "Pfeil"), U.S. Patent No. 4,135,935

Initially, Applicants respectfully submit that the rejection was previously based upon anticipation, but is presently based upon anticipation and obviousness. However, the rejection does not provide any indication as to any basis for an obviousness rejection. For example, the rejection does not set forth the differences between Pfeil and Applicants' claimed subject matter, does not indicate what changes are being made to Pfeil to arrive at Applicants' claimed subject matter, and does not provide any motivation for making any changes to Pfeil to arrive at Applicants' claimed subject matter.

Accordingly, if the obviousness rejection is maintained, the basis for the rejection should be explained. In such an instance, it would be expected that the next action would not be final.

Moreover, it is noted that claims 10, 20 and 21 have been canceled, whereby the rejection of these claims is moot

Applicants' independent claim 1 is directed to a sintered calcium phosphate comprising a bioactive glass as a sintering aid, said bioactive glass having a composition substantially comprising 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and 20 mol % or less of Na₂O, wherein said bioactive glass is free from P₂O₅, and said sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapapite, a carbonated apatite or tricalcium phosphate.

Accordingly, independent claim 1 recites amongst other features:

- (1) a sintered calcium phosphate comprising a bioactive glass as a sintering aid,
 - (2) the bioactive glass is free from P₂O₅,
- (3) the bioactive glass having a composition substantially comprising 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and 20 mol % or less of Na₂O, and
- (4) the sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapatite, a carbonated apatite or tricalcium phosphate.

The sintered calcium phosphate comprising a bioactive glass as a sintering aid makes it possible to deposit ß-wollastonite crystals having a needle-like structure at a

crystallization temperature so as to provide a sintered calcium phosphate excellent in biocompatibility and mechanical strength (such as discussed in Applicants; specification at page 5, line 24 to page 6, line 4; page 20, lines 14-17; and page 21, lines 4-7), particularly suitable for the cell attachment, cell proliferation and alkaline phosphotase activity in the cell culture as described in Example 9 of Applicants' specification (see Applicants' specification at page 19, line 16 to page 20, line 17; and Tables 5 and 6 at page 20).

In contrast, Pfeil discloses, in his Example, a ground glass of the following composition, in weight percent: 46.2 % of SiO₂, 25.5% of Ca₃(PO₄)₂, 20.2% of CaO, 2.9% of MgO, 4.8% of Na₂O, and 0.4% of K₂O (see column 7, lines 55-65), which corresponds to a composition, in mol %: 56.3 % of SiO₂, 6.0% of Ca₃(PO₄)₂, 26.4% of CaO, 5.39% of MgO, 5.7% of Na₂O, and 0.4% of K₂O. Accordingly, Example 1 of Pfeil does not teach or suggest Applicants' bioactive glass which includes, amongst other features substantially 30 to 60 mol % of CaO.

Moreover, as is clear from claim 1 of Pfeil, Pfeil discloses a glass of the following composition as a second sintering material B, in weight %: about 20% to about 60% of SiO_2 , about 5% to about 40% of P_2O_5 , about 2.7% to about 20% of Na_2O , about 0.4% to about 20% of K_2O , about 2.9% to about 30% of MgO, and about 5% to about 40% of CaO.

Therefore, such as composition does not teach or suggest at least a sintered calcium phosphate comprising a bioactive glass as a sintering aid, a bioactive glass free

from P_2O_5 , or the sintered calcium phosphate containing a calcium phosphate comprising a hydroxyapatite, a carbonated apatite or tricalcium phosphate.

Accordingly, Pfeil does not teach or suggest each and every feature recited in Applicants' claim 1, and claims dependent therefrom.

Independent claim 12 is directed to a sintered calcium phosphate comprising a bioactive glass as a sintering aid, said bioactive glass having a composition consisting essentially of 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and 0.1-5 mol % of Na₂O, wherein said sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapapite, a carbonated apatite or tricalcium phosphate.

Accordingly, Pfeil does not teach each and every feature of independent claim 12 and the claims dependent therefrom. For example, independent claim 12 recites that the bioactive glass has a composition consisting essentially of 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and 0.1-5 mol % of Na₂O. However, the rejection does not address the consisting essentially language included in the claims. Therefore, if this ground of rejection is maintained, the Examiner is respectfully requested to indicate how any composition disclosed by Pfeil includes the combination of features including a bioactive glass having a composition consisting essentially of 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and 0.1-5 mol % of Na₂O.

Therefore, the rejection of independent claim 12 and dependent claims 15, 18 and 25 should be withdrawn.

Applicants' arguments regarding the patentability Independent claim 14 are similar to those with respect to independent claim 12. Moreover, claim 14 includes, amongst other features a bioactive glass having a composition consisting essentially of 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, 0.1-5 mol % of Na₂O, and B₂O₃. In contrast, Pfeil does not teach a bioactive glass including B₂O₃. Accordingly, Pfeil does not teach each and every feature of independent claim 14.

The rejection asserts that B_2O_3 is optional. However, claim 14 explicitly recites B_2O_3 as a positive recitation, and is therefore present in Applicants' composition. While an amount is not recited in the claim, the component is present. Accordingly, the rejection of claim 14 is without appropriate basis, and the rejection should be withdrawn.

(b) Rejection of claims 1-3, 5-11, 16, 19, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fujiu et al. (hereinafter "Fujiu"), U.S. Patent No. 4,708,652

Initially, Applicants note that claim 10 has been canceled, whereby the rejection of this claim is moot.

Applicants once again note that Fujiu discloses an apatite composite ceramic obtained by reaction-sintering at a sintering temperature of 700-1100°C at a pressure of at least atmospheric pressure a powder mixture of a synthetic hydroxyapatite (A) and a biological active glass (B) containing fluoride ions and having a crystallization temperature below the sintering temperature in a weight ratio of A/B ranging from 60/40

to 30/70. The reaction sintered material of Fujiu is disclosed to have excellent biological affinity and high mechanical strength. Fujiu also discloses that the biological active glass (B) is selected from the scope of the following composition (disclosed in U.S. Patent No. 4,437,192): 35-60 mol % of Si0₂, 0-15 mole % of B₂O₃, 10-30 mol % of Na₂O, 5-40 mol % of CaO, 0-1 mol % of Ti0₂, 0-15 mol % of P₂O₅, 0-20 mol% of K₂O, 0-10 mol% of Li₂O, 0-5 mol % of MgO, 0-8 mol % of (Al₂O₃ + ZrO₂ \pm Nb₂O₅), 0-8 mol % of (La₂O₃ + Ta₂O₅ + Y₂O₃) and 5-20 mol % of F₂ (see Abstract, claims 1 and 4, and column 3, lines 35 et seq. of Fujiu).

Reviewing the specific Example of Fujiu at column 5, beginning at line 57, the biologically active glass powder is disclosed as including 46.1 mol % of Si0₂, 24.4 mol % of Na₂0, 13.5 mol % of CaO, 13.4 mol % of CaF₂ and 2.6 mol % P₂0₅. Moreover, in the Comparative Examples, Fujiu discloses a biologically active glass not containing fluoride ions including 46.1 mol % of Si0₂, 24.4 mol % of Na₂0, 26.9 mol % of CaO and 2.6 mol % P₂0₅.

Also, in the Examples of U.S. Patent No. 4,437,192 (which as noted above is referenced in Fujiu and a copy of which is submitted herewith to assist the Examiner's review of this patent and is being listed on the attached Form PTO-1449), the mol % of CaO is apparently disclosed as a highest value of 15 mol %. Moreover, for examples of Na₂O in U.S. Patent No. 4,437,192, many examples include Na₂O above 20 mol %. For examples, 10 and 12, Na₂O is below 20 mol %; however, the mol % of CaO is lower in these examples.

In contrast to the disclosure of Fujiu, Applicants' independent claim 1 is directed to a sintered calcium phosphate comprising a bioactive glass as a sintering aid, said bioactive glass having a composition substantially comprising 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and 20 mol % or less of Na₂O, wherein said bioactive glass is free from P₂O₅, and said sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapapite, a carbonated apatite or tricalcium phosphate.

Accordingly, independent claim 1 recites amongst other features:

- (1) a sintered calcium phosphate comprising a bioactive glass as a sintering aid,
 - (2) the bioactive glass is free from P_2O_5 ,
- (3) the bioactive glass having a composition substantially comprising 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and 20 mol % or less of Na₂O, and
- (4) the sintered calcium phosphate contains a calcium phosphate comprising a hydr2oxyapatite, a carbonated apatite or tricalcium phosphate.

Fujiu is silent with respect to a bioactive glass being a sintering aid in a sintered calcium phosphate. Moreover, Fujiu does not discuss a bioactive glass having cell attachment, cell proliferation and alkaline phosphotase activity as described in Example 9 of the present application.

Still further, Fujiu discloses broad ranges of components, <u>but does not sufficiently</u> envisage to anticipate or render obvious the compositions recited in Applicants' claims.

There is absolutely no motivation in Fujiu to pick and choose from the various ranges

Applicants' claimed subject matter. This is especially apparent from a review of the specific examples of Fujiu, such as disclosed in U.S. Patent No. 4,437,192 referenced at column 3, lines 35-53 of Fujiu.

Still further, Applicants note that the bioactive glass of Applicants' independent claim 1, and claims dependent thereon, include such features that when the bioactive glass as a sintering aid makes it possible to deposit β-wollastonite crystals having a needle-like structure at a crystallization temperature so as to provide a sintered calcium phosphate glass excellent in biocompatibility and mechanical strength (see page 5, lines 24-28; and page 20, lines 14-17 of Applications' specification), particularly suitable for the cell attachment, cell proliferation and alkaline phosphotase activity in the cell culture as described in Example 9 of Applicants' application (see page 19, line 16 to page 20, line14; and Tables 5 and 6 at page 20 of the Applicants' specification.

Moreover, the dependent claims further patentably define the subject matter recited in Applicants' independent claims. Accordingly, these claims are patentable over Fujiu for the features recited in the independent claims as well as the further features recited in the dependent claims.

Similar arguments apply to independent claims 7 and 17 and the claims dependent therefrom. Fujiu discloses broad ranges of components, but does not sufficiently envisage to anticipate or render obvious the compositions recited in Applicants' claims. There is absolutely no motivation in Fujiu to pick and choose from the

various ranges disclosed therein (and further disclosed in U.S. Patent No. 4,437,192) to arrive at Applicants' claimed subject matter. Again, Applicants note that this is especially apparent from a review of the specific examples of Fujiu, such as disclosed in U.S. Patent No. 4,437,192 referenced at column 3, lines 35-53 of Fujiu. Thus, there is no motivation to arrive at the various compositions recited by Applicants including each alternative recited therein.

Still further, the rejection is without sufficient basis in not addressing the "consisting essentially" language recited in independent claim 17. Therefore, if this ground of rejection is maintained, the Examiner is respectfully requested to indicate how any composition disclosed by Fujiu includes the combination of features including a bioactive glass having a composition consisting essentially of 30 to 60 mol % of CaO, 40 to 70 mol % of SiO₂, and at least one of Na₂O, CaF₂ and B₂O₃, Na₂O being 0.1 to 5 mol %, CaF₂ being 0.1-1 mol %, and B₂O₃ being 5 mol % or less.

Therefore, those skilled in the art referring to Fujiu would not be motivated to arrive at Applicants' claimed subject matter. Accordingly, this ground of rejection should be withdrawn.

(c) Rejection of claims 1, 2, 4-9, 17, 19, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suh et al. (hereinafter "Suh"), U.S. Patent No. 5,634,956.

Initially, Applicants respectfully submit that the rejection was previously based upon anticipation, but is presently based upon anticipation and obviousness. However, the rejection does not provide any indication as to any basis for an obviousness rejection. For example, the rejection does not set forth the differences between Suh and Applicants' claimed subject matter, does not indicate what changes are being made to Suh to arrive at Applicants' claimed subject matter, and does not provide any motivation for making any changes to Suh to arrive at Applicants' claimed subject matter. Accordingly, if the obviousness rejection is maintained, the basis for the rejection should be explained. In such an instance, it would be expected that the next action would not be final.

Moreover, it is noted that claim 10 has been canceled, whereby the rejection of this clam is moot.

Suh discloses a glass ceramic for use as a biomaterial comprising CaO 34.6 to 54.6%, SiO_2 24.2 to 44.8 %, P_2O_5 0 to 8.0 %, CaF_2 0.1 to 1.0 % and MgO 1.0 to 10.0 % by weight, the glass ceramic having a primary crystalline phase which is wollastonite (CaO, SiO_2) and a secondary apatite crystalline phase which can be an apatite without adding the glass ceramic as such to calcium phosphate (see Abstract; column 2, lines 10-15; column 3, lines 38-40 and lines 46-49 (Examples I and 2 of Suh).

Applicants once again respectfully submit that Suh fails to teach or suggest any feature such that the glass ceramic as such might have a function to promote the sintering in the process of sintering calcium phosphate, even when the glass thereof is added to calcium phosphate.

Still further, Suh does not disclose a bioactive glass being a sintering aid in a sintered calcium phosphate.

In any event, the independent claims presently recite, amongst other features recited therein, wherein said sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapapite, a carbonated apatite or tricalcium phosphate.

Accordingly, the rejection based upon Suh is without sufficient basis and should be withdrawn.

(d) Rejection of claims 13 [1-3], 5-9, 12-19, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Japanese document 61-205637 (JP'637)

Initially, Applicants respectfully submit that the rejection was previously based upon anticipation, but is presently based upon anticipation and obviousness. However, the rejection does not provide any indication as to any basis for an obviousness rejection. For example, the rejection does not set forth the differences between JP'637 and Applicants' claimed subject matter, does not indicate what changes are being made to JP'637 to arrive at Applicants' claimed subject matter, and does not provide any

motivation for making any changes to JP'637 to arrive at Applicants' claimed subject matter. Accordingly, if the obviousness rejection is maintained, the basis for the rejection should be explained. In such an instance, it would be expected that the next action would not be final.

Moreover, it is noted that claims 10 and 20 have been canceled, whereby the rejection of these claims is moot

JP'637 discloses a composition of a crystal glass comprising at least 90 wt% or more comprising 40-60 wt% Si0₂, 30-45 wt% CaO, 1-17 wt% MgO, and 10 wt% or less of impurities and a minute wollastonite (CaO.Si0₂) crystals dispersed in the crystal glass as at least one of the deposited crystals (see English abstract of JP '637 and Table I in JP'637).

Applicants once again respectfully submit that JP '637 fails to teach or suggest any feature such that the glass ceramic as such might have a function to promote the sintering in the process of sintering calcium phosphate.

Still further, JP '637 does not disclose a bioactive glass being a sintering aid in a sintered calcium phosphate.

In any event, the independent claims presently recite, amongst other features recited therein, wherein said sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapapite, a carbonated apatite or tricalcium phosphate.

Accordingly, the rejection based upon JP '637 is without sufficient basis and should be withdrawn.

(e) Claims 12, 14, 15, 17-20 and 25 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kume et al. (hereinafter "Kume"), U.S. Patent No. 4,443,550

Initially, Applicants respectfully submit that the rejection was previously based upon anticipation, but is presently based upon anticipation and obviousness. However, the rejection does not provide any indication as to any basis for an obviousness rejection. For example, the rejection does not set forth the differences between Kume and Applicants' claimed subject matter, does not indicate what changes are being made to Kume to arrive at Applicants' claimed subject matter, and does not provide any motivation for making any changes to Kume to arrive at Applicants' claimed subject matter. Accordingly, if the obviousness rejection is maintained, the basis for the rejection should be explained. In such an instance, it would be expected that the next action would not be final.

Moreover, it is noted that claim 20 has been canceled, whereby the rejection of this claim is most

Kume discloses a glass composition for production of a fibrous wollastonite used as a reinforcing material for Portland cement. etc., which has the composition comprising 35-60 wt% SiO₂, 30-55 wt% CaO, 0-8 wt% (Na₂O + K₂O). 1-30 wt% B₂O₃, 0.2-4 wt% Li₂O and 0-8 wt% Al₂O₃, wherein at least one of Li₂O, Al₂O₃, and Na₂O is present (see claim I with Certificate of Correction attached to Kume), whose features are different from the those of claim 12 of the present application in not disclosing the use of 0.1-5 mol % of

Application No. 10/618,687

Na₂0 and any bioactive glass to be used for a sintering aid in a sintered calcium phosphate glass, but in disclosing the use of Li₂0 with or without presence of Al₂0₃.

Applicants once again respectfully submit that Kume '637 fails to teach or suggest any feature such that the glass ceramic as such might have a function to promote the sintering in the process of sintering calcium phosphate.

Still further, Kume does not disclose a bioactive glass being a sintering aid in a sintered calcium phosphate.

In any event, the independent claims presently recite, amongst other features recited therein, wherein said sintered calcium phosphate contains a calcium phosphate comprising a hydroxyapapite, a carbonated apatite or tricalcium phosphate.

Accordingly, the rejection based upon Kume is without sufficient basis and should be withdrawn.

(f) Rejection of claims 1-3, 5, 7, 9-15, 17-22, 24 and 25 under the judicially created doctrine of obviousness-type double patenting over claims 1-11 of copending Application No. 10/962,557

In response to this ground of rejection, Applicants note that Application No. 10/962,557 is pending, and has been allowed with a Notice of Allowance being mailed on July 10, 2006.

Applicants respectfully request the Examiner to reconsider the double patenting rejection based upon the merits in view of the presently pending claims and the allowed

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claims in Application No. 10/962,557. In this regard, if the rejection is maintained, the Examiner is respectfully requested to contact the undersigned by telephone to discuss the same with a view towards advancing the application to allowance.

Also, Applicants respectfully once again submit that, in conformance with Patent and Trademark Office procedure and in view of the fact that Application No. 10/962,557 is not a patent, the present application can be sent to issue.

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

> Respectfully submitted, SAWA et al.

Bruce H. Bernstein Reg. No. 29,027

August 14, 2006 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191



GREENBLUM & BERNSTEIN, P.L.C. Intellectual Property Causes 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191



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The Patent Office Date stamp hereon is an acknowledgement that, on the date indicated, the Patent Office received the following:

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